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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,900	03/19/2004	J. Kenneth Burkus	4002-3501/PC361.18	8205

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,900

Applicant(s)

BURKUS ET AL.

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20-60 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/19/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claims 35, 45, and 59 are objected to because of the following informalities:

In claim 35, line 1, "in" should be removed.

In claim 45, line 1, "for" should be removed.

In claim 59, line 1, "for" should be removed.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 41, 42, and 46-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation "...said medial side thereof..." in lines 2 and 3.

There is insufficient antecedent basis for this limitation in the claim.

Claims 41, 42, 46 and 53 recite, "...a lateral surface opposite the other of first and second distractor tips..." It is unclear what "the other" is referring to.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-60 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claims 20, 39, 46, and 53, applicant positively recites part of a human, i.e. "corresponding to a curvature of an inner portion of a cortical rim of vertebral endplates in a sagittal plane." Thus claims 20-60 include a human within their scope and are non-statutory.

Claims 37-38, 42, 49, and 53-60 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claims 37, 42, 49 and 53 applicant positively recites part of a human, i.e. "corresponding to a curvature of the inner portion of a cortical rim of vertebral endplates in a coronal plane." Thus claims 20-60 include a human within their scope and are non-statutory

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In *re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-23 and 25-60, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (US Pat. 5,505,732).

Michelson discloses a surgical instrument assembly for distracting a spinal disc space, comprising: a first distractor (100, Fig. 7F) including a first shaft (100, Fig. 7F) extending between a proximal end and a distal end; a first distractor tip (102, Fig. 7F) extending from the distal end of said first shaft, said first distractor tip including opposite first (Fig. 3D, below) and second surfaces (Fig. 3D, below) defining a first distraction height; a second distractor including a second shaft (100, Fig. 7F) extending between a proximal end and a distal end; a second distractor tip extending from the distal end of said second shaft (102, Fig. 7F), said second distractor tip including opposite first (124, Fig. 3) and second surfaces (124, Fig. 3) defining a second distraction height substantially equal to said first distraction heights, wherein at least one of said first and second distractor tips includes a first transition surface (Fig. 3D, below) extending between a distal end surface (Fig. 3D, below) and said first surface (Fig. 3D, below) of said at least one distractor tip and a second transition surface (Fig. 3D, below) extending between said distal end surface and said second surface (Fig. 3D, below) of the at least one distractor tip said first and second transition surfaces each having a curvature (Fig. 3D, below); a guide sleeve (340, Fig. 7D) defining a working channel (348, Fig. 7F) extending between a proximal end and a distal end, wherein said first and second distractors are received in said working channel of said guide sleeve (Fig. 7F), and a distractor driver cap (135, Fig. 2) coupled to the proximal end of said first and second distractors and said guide sleeve, said distractor driver cap having a side opening (138, Fig. 2) wherein said distractor driver cap is side-loaded onto said first and second distractors and said guide sleeve. The second distractor includes a recessed

Art Unit: 3733

area extending along a medial side thereof (Fig. 3, below). The recessed area is a concave surface (Fig. 3, below). The first distractor includes a convex surface along said medial side thereof (Fig. 3, below), and said second distractor includes a convex surface along said medial side thereof (Fig. 3, below). A distal end of said guide sleeve includes a pair of opposite flanges (342, Fig. 7D) extending distally therefrom. The working channel includes a first working channel portion for receiving said first distractor and a second working channel portion for receiving said second distractor (340, Fig 7c). The first working channel portion and the second working channel portion form a figure eight shape (340, Fig 7c). The guide sleeve includes a sleeve cap (344, Fig. 7F) at said proximal end of said guide sleeve, said sleeve cap including a proximal end ring (344, Fig. 7F) engageable to said distractor driver cap.

The first distractor includes a first flange (110, Fig. 7F) on its proximal end defining a lip therearound and said second distractor includes a second flange (110, Fig. 7F) on its proximal end defining a lip therearound. The lips can be considered to be the edge of both of the flanges. The driver cap (420, Fig. 7E) including a distractor slot slidably receiving said first and second flanges therein (Fig. 7F). The distractor driver cap includes a guide sleeve slot (354, Fig. 7F) that can slidably receive said proximal end ring. The first flange includes a proximal face having a hole (117, Fig. 2) therein and the second flange includes a proximal face having a hole therein (117, Fig. 2), the distractor driver cap including a spring-biased plunger (column 18, lines 63-67) positionable in a corresponding one of said holes when said distractor driver cap is properly positioned thereon. The first distractor includes a projection (116, Fig. 2)

Art Unit: 3733

extending from a medial side of said first shaft, the second distractor includes a notch (132, Fig. 2) formed in a medial side of said second shaft, when said first and second distractors are positioned in said guide sleeve said projection is received in said notch to prevent relative movement between said first and second distractors. The projection is cylindrically shaped (116, Fig. 2). Each of said first and second distractor tips includes: a distal end surface (Fig. 3D, below), a lateral surface (Fig. 3D, below), a third transition surface (Fig. 3D, below) extending between said distal end surface and said lateral surface, the third transition surface having a second curvature (Fig. 3D, below). Each of said first and second distractor tips further includes a fourth transition surface (Fig. 3D, below) extending between said lateral surface and said first surface and a fifth transition surface (Fig. 3D, below) extending between said lateral surface and said second surface, said fourth and fifth transition surface each having a third curvature. Each of said first and second distractor tips further includes said first transition (Fig. 3D, below) surface extending between said distal end surface and said upper first surface (Fig. 3D) and said second transition surface extending between said distal end surface and said second surface (Fig. 3D), said first and second transition surface each having said curvature.

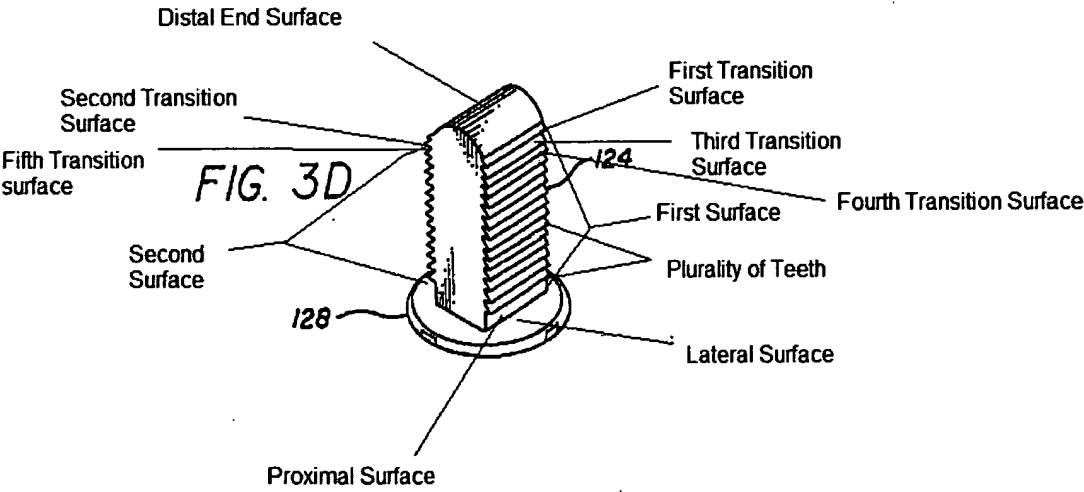
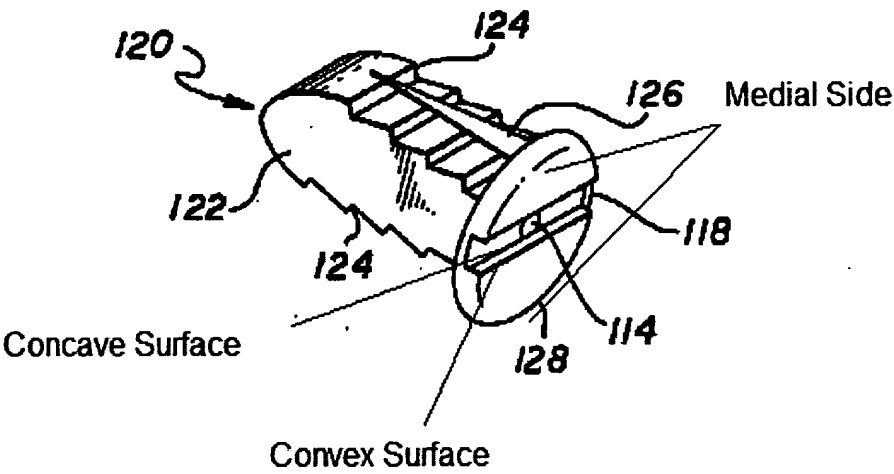
The at least one of said first and second distractor tips includes: a lateral surface (Fig. 3D, below) opposite the other of said first and second distractor tips when positioned therealong; and a third transition (Fig. 3D, below) surface extending between said distal end surface and said lateral surface, said third transition surface having a second curvature (Fig. 3D, below) generally corresponding to a curvature of the inner

Art Unit: 3733

portion of the cortical rim of vertebral endplates in an axial plane; a fourth transition surface (Fig. 3D, below) extending between said lateral surface and said second surface, said third and fourth transition surfaces each having a second curvature (Fig. 3D, below). The distal end surface of said at least one of said first and second distractors is linear and orthogonal to a central longitudinal axis of said at least one distractor (Fig. 2). The first and second surfaces of said at least one distractor tip each include a plurality of teeth formed therein (Fig. 3D, below).

The at least one of said first and second distractors said first surface includes a proximal portion (closer to the lateral surface in Fig. 3D) a distal portion (closer to the distal end portion in Fig. 3D) and said second surface includes a proximal portion (closer to the lateral surface in Fig. 3D) and a distal portion (closer to the distal end portion in Fig. 3D), said proximal portions being generally parallel with one another and said distal portions tapering toward one another from said proximal portions toward said distal end surface. The proximal portions are parallel and the distal portions taper towards one another (122, Fig. 3A).

FIG. 3



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Pat. 5,505,732).

Michelson discloses the claimed invention except for the distractor tips being formed integrally with their respective shafts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the tips integrally with their respective shafts, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

With regard to the statements of intended use and other functional statements (e.g. "...is side loaded...", "...for receiving said first distractor...", "...engageable to said distractor...") they do not impose any structural limitations on the claims distinguishable over the surgical instrument assembly for distracting a spinal disc space of Michelson, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, the law of anticipation does not require that the reference "teach" what the

Art Unit: 3733

subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



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SUPERVISORY PATENT EXAMINER